

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA File Symbol: 2724-IGU /RF2185 CSO XM
PC Code: 128965

From: Mark Perry, Lead Biologist *MJP*
RMIBV
Pesticide Re-evaluation Division (7508P)

Thru: Marianne Lewis, Biologist *ML 11/20/12*
Insecticides/Rodenticides Branch
Registration Division (7505P)

To: R. Gebken, PM 10
Insecticide Branch
Registration Division (7505P)

Applicant: Wellmark Int.
1501 E. Woodfield Rd. Suite 200W
Schaumburg, IL 60193

Formulation from EPA File Symbol 2724-IGU Label:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Etofenprox	40.0%
<u>Inert Ingredient(s):</u>	60.0%
Total	100.0%

BACKGROUND: The registrant is citing acute toxicity studies to support the registration of their new product, File Symbol 2724-IGU. The MRID's are as follows: 46513404 (81-1), 46513405 (81-2), 48475802 (waiver request, 81-3), 46513406 (81-4), 46513407 (81-5), and 46513408 (81-6). These studies and a similar waiver request were reviewed and found to be acceptable under EPA Reg. No. 2724-504 by TRB/RD on 5/24/05.

For product chemistry requirement the registrant is citing a combination of existing and new data including MRIDs 48891301 and 46513403. For the purposes of this screen the cited data appear appropriate for this product, however a full product chemistry review is required by the Technical Review Branch.

RECOMMENDATIONS: After reviewing the studies and the CSF's for the subject product and the product tested in the studies, the Agency will allow the registrant to cite the acute toxicity studies listed above to support the registration of the subject product. The acute toxicity profile for EPA File Symbol 2724-IGU is currently:

Acute Oral	IV	Cited
Acute Dermal	IV	Cited
Acute Inhalation	IV	Waived
Primary Eye	IV	Cited
Primary Dermal	IV	Cited
Skin sensitization	non sensitizer	Cited

LABELING: For precautionary labeling, see the labeling section in the review referenced above.



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MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in blue ink, appearing to read "Kevin Sweeney", with a checkmark at the end.

Date: April 3, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 407641

Decision no.: 470118

Submission no: 924373

Action code: R310

Product Name: RF2185 CSO XM

EPA Reg. No or File Symbol: 2724-IGU

Formulation Type: RTU spot-on for cats

Ingredients statement from the label with PC codes: 40.0% etofenprox (pc code 128965)

Application rate: spot-on based on number of vials per unit weight

Use pattern: cat spot-on

OCSPP Guidelines: 810.3300

I. Action Requested: Review cited efficacy data and new product label.

II. Background: Registrant cited the efficacy studies used to support EPA Reg. No 2724-504. Unlike the EPA Reg. No. 2724-796, this product contains the adulticide component only – etofenprox. There is no S-methoprene in the new product and no IGR claims are made. The application rate of the adulticide component is the same as for EPA Reg. No. 2724-504. The label claims of the new product are the same as those for EPA Reg. No. 2724-504 except that the IGR claims have been removed.

III. Study Reviews

The cited studies are: MRIDs 46513410, 46513411, 46513412, 46513413, 46513414, and 46513415. All of the cited data, which also support EPA Reg. No. 2724-504, have already been reviewed by the EPA. Attached please find a DER by Kevin Sweeney for the cited data. A copy of the most recently accepted label for EPA Reg. No. 2724-504 is also attached

Conclusion: the cited studies are acceptable.

IV. Entomologist's Recommendations:

1. The proposed label is acceptable provided that the registrant:
 - a. Removes all prevention and long-term control claims for fleas from the label as there is no IGR in the formula:
 - “[Advanced] Spot-on [Plus] Insect Control [treatment and prevention]” – this is an adulticide only product.
 - “A flea control program” – there is no IGR in the formulation.
 - “Long lasting, flea, deer tick, and mosquito protection” – there is no IGR component.
 - “Flea prevention is the best flea control strategy.”
 - On page 3 remove all “prevention claims” There is no IGR in the formula.